REMARKS

This submission is in response to the Official Action dated August 15, 2001 and submitted concurrently with a Request for Continued Examination and Information Disclosure Statement. Claim 1 has been amended to clarify which members of the variable B substituent group may be combined to produce a ring that is fused to the phenyl ring of variable B. Claim 21 has been amended to delete the first named species. No new matter has been added by these amendments.

Claims 1-5 and 19-21 are pending. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

35 USC §112, second paragraph rejection

The Examiner has rejected claims 1, 2, 4, and 5 for failing to particularly point out and distinctly claim the invention. The Examiner contends that it is not clear what the second ring fused to the benzene ring is. Applicants request reconsideration.

Claim 1 has been amended to clarify that when B is substituted with two members of the group consisting of alkyl, alkoxy, amino, alkylsulfonylamino or alkylamino *and* the two members are adjacent to each other, the substituents may be connected together to form a ring fused to the phenyl. Applicants submit that the claim, as amended, clearly states what substituents may be combined to produce the fused ring. Accordingly, Applicants request that the rejection be withdrawn.

35 USC § 103

The Examiner has rejected claim 21 as being unpatentable over Ward. The Examiner contends that the first species in claim 21 is rendered obvious for reasons of record.

In response to this rejection, Applicants have deleted the first species in claim 21. Therefore, Applicants request that the rejection be withdrawn.

The Examiner has rejected claims 1, 2, 4, and 5 as being unpatentable over Plilai in view of van der Stelt. The Examiner contends that the difference between a hydrogen and a methyl is not a patentable difference. Applicants request reconsideration.

Plilai discloses that none of these compounds showed any noteworthy activity (see page 714, abstract). The Examiner contends that the effects produced by the presence of a hydrogen atom and a methyl would be similar. Therefore, one of ordinary skill in the art would have concluded that replacement of a hydrogen with an alkyl would not have significantly affected the activity of these compounds and thus these compounds would not have been predicted to exhibit any noteworthy activity. Comparatively, the claimed compounds disclose significant activity (see Tables 1 and 2). Thus, the activities observed for these compounds are unexpected and surprising in view of the prior art. Accordingly, the compounds of the present invention are not obvious in view of Plilai and van der Stelt. Therefore, Applicants respectfully request

that the rejection be withdrawn.

35 USC §102(b)

Claims 1, 2, 4, and 5 have been rejected as being anticipated by Patel, Ananthanarayanan, and Vadodaria. The Examiner contends that the compounds of the present invention are disclosed in these references. Applicants request reconsideration.

Patel and Vadodaria both indicate that a chlorine substituent is required at the 3-position of one of the aromatic rings (Ar or Ar' in the present claims). No such substitution pattern is encompassed by the present claims (see definition of Ar and Ar' in claim 1). Therefore, these references do not anticipate the present claims.

In response to the Examiner's rejection of the claims in view of Ananthanarayanan, Applicants have amended proviso 4 in claim 1 to state that when Y is a CH or nitrogen atom and each of Ar and Ar' are optionally substituted phenyl where the substitution is methyl, then B cannot be unsubstituted phenyl. This proviso excludes compounds that are encompassed by Ananthanarayanan. Accordingly, Applicants request that the rejection be withdrawn.

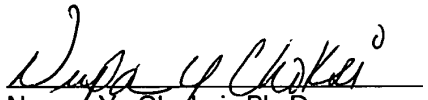
CONCLUSIONS

Therefore, in view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed

and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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Docket No: 6485/1D340-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Leonardi et al.

Serial No.: 09/127,059 Art Unit: 1624

Confirmation No.:

Filed: 07/31/98 Examiner: E. Bernhardt

For: DIARYLALKYLPIPERAZINES ACTIVE ON THE LOWER URINARY TRACT

MARK-UP VERSION FOR RESPONSE TO OFFICIAL ACTION UNDER 37 CFR §1.116

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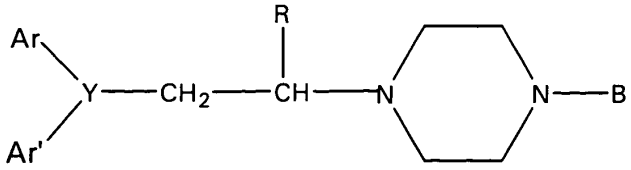
1. (Amended) A compound of the formula



wherein

each of Ar and Ar' is independently chosen from a group consisting of phenyl and pyridyl each optionally substituted by one or more members from the group consisting of alkyl, alkoxy, cyano, nitro, amino, alkylsulfonylamino, or alkylamino;

Y is chosen from the group consisting of a nitrogen atom, a CH, C-OH, C-CN, or a C-$CONH_2$ group;

R is a hydrogen atom or a lower alkyl group;

B is phenyl, optionally substituted by one or more members selected from the group consisting of alkyl, alkoxy, halogen, cyano, nitro, amino, alkylsulfonylamino, and alkylamino; wherein when the phenyl ring is substituted with <u>two members of the group consisting of alkyl, alkoxy, amino, alkylsulfonylamino or alkylamino and the two members are adjacent to each other</u> [two members of the group], the substituents may be connected together to form a ring fused to the phenyl with the provisos that

1) when B is methoxyphenyl and Y is any of C-CN, and C-$CONH_2$ then Ar and Ar' are not simultaneously unsubstituted phenyl;

2) when Y equal CH, Ar and Ar' cannot both be optionally substituted pyridyl;

3) when Y equal CH and one of Ar and Ar' equal optionally substituted phenyl, the other of Ar' and Ar cannot equal optionally substituted pyridyl; and

4) when Y = CH <u>or nitrogen atom</u> and each of Ar and Ar' are

optionally substituted phenyl wherein said substitution is methyl, then B cannot be unsubstituted phenyl,

and enantiomers, diastereomers, N-oxides crystalline forms, hydrates and pharmaceutically acceptable salts thereof.

21. (Amended) A compound selected from the group consisting of

[1-[3,3-bis-(2-pyridyl)propyl]-4-(2-methoxyphenyl)piperazine;]

1-[3-hydroxy-3,3-bis-(2-pyridyl)propyl]-4-(2-methoxyphenyl)piperazine;

1-(4-1H-indolyl)-4-[3,3-bis-(2-pyridyl)propyl]piperazine;

1-[3-cyano-3,3-bis-(2-pyridyl)propyl]-4-(2-methoxyphenyl)piperazine;

1-[3-cyano-3-phenyl-3-(2-pyridyl)propyl]-4-(2-methoxyphenyl)piperazine; and

1-[N-(2-nitrophenyl)-N-(2-pyridyl)-2-aminoethyl]-4-(2-methoxyphenyl)piperazine.